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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	430156.401USPC	7156

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

DAHLE, CHUN WU

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

06/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,341

Applicant(s)

JUNG ET AL.

Examiner

CHUN DAHLE

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I and species of SEQ ID NO:8 encompassing claims 1-7 and 13 in the reply filed on February 15, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-13 are pending.

Claims 8-12 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b) as being drawn to nonelected invention.

Claims 1-7 and 13 are currently under consideration as they read on the elected invention of an Fc fragment and SEQ ID NO:8.

2. Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) based on application REPUBLIC OF KOREA 10-2003-0080299, is acknowledged (See Application Data Sheet mailed on May 18, 2005). It is noted, however, that applicant has not filed certified copies of the application as required by 35 U.S.C. 119(b). Consequently, the claims have been accorded the priority of the filing date of the PCT/KR04/02942, i.e. 11/13/2004.

3. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 6 fails to limit the subject matter of the previous claim 5. The previous claim 5 recites "an aglycosylated IgG4 Fc fragment", while dependent claim 6

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encompasses "a human-derived aglycosylated IgG4 Fc fragment". The recitation of "derived" would open the claim to any aglycosylated Fc fragment, e.g. IgG1 Fc fragment. See rejection discussed below in Section 7.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (WO 01/03737, reference on PTO 892 mailed on November 15, 2007).

Cox et al. teach an Fc fragment, e.g. Fc fragment from human IgG4, and a pharmaceutical composition comprising said Fc fragment linked to therapeutic factors such as G-CSF (e.g. see Example 1 on pages 11-18). Given that the instant SEQ ID NO:8 is the amino acid sequence of Fc region of IgG4, the prior art teachings of IgG4 Fc region would read onto claim 7 encompassing SEQ ID NO:8.

In addition, the instant claim 7 recites "an amino acid sequence represented by SEQ ID NO:8". Applicant is notified that recited "an amino acid sequence represented by SEQ ID NO:8" encompasses amino acid sequence comprise the full-length of SEQ ID NO: 8 or any portion of the SEQ ID NO: 8. The claim is anticipated by any amino acid sequences with two or more residues from SEQ ID NO:8. Amending the claims to recite "the amino acid sequence consisting of SEQ ID NO:8" would read on the entire SEQ ID NO:8.

Therefore, the reference teachings anticipate the claimed invention.

6. Claims 1-7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (EP0227110) as evidenced by page 17 of the instant specification.

Nakamura et al. teach recombinant human IgG Fc region including Fc region from IgG2 and IgG4 made from *E. coli* host cells (e.g. see page 2 and Examples on pages 6-12). Further, Nakamura et al. teach pharmaceutical composition comprising said human Fc region in well-known carriers such as PBS (e.g. see page 13). Given that it was well-known in the art that *E. coli* host cells lack glycosylation enzymes for modifying human proteins, the prior art Fc made in *E. coli* host cells would be aglycosylated.

Therefore, the reference teachings anticipate the claimed invention.

7. Claims 1, 4, 6, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jendeberg et al. (J. Immunol. Method. 1997. 201:25-34).

Jendeberg et al. teach recombinant Fc fragment from human IgG made in *E. coli* host cells (e.g. see pages 29). Jenderberg et al. further teach Fc fragment in well-known carriers such as NaCl (e.g. see left column on page 30). Given that it was well-known in the art that *E. coli* host cells lack glycosylation enzymes for modifying proteins, the prior art Fc made in *E. coli* host cells would be aglycosylated.

It is noted that instant claim 6 recites "a human-derived aglycosylated IgG4 Fc fragment". Given that the instant specification does not disclose what the recited "derived" represents, "a human-derived aglycosylated IgG4 Fc fragment" would read onto any IgG Fc region, including IgG1 or IgG3 Fc fragment.

Regarding the intended use of "a drug carrier" recited in independent claim 1, it is noted that the intended uses of Fc fragment as "a drug carrier" do not carry patentable weight per se and the claims read on the active or essential ingredient which is Fc fragment.

Therefore, the reference teachings anticipate the claimed invention.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-7 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-13 of copending USSN 10/535,231, and

claims 1-19 and 27-44 of copending USSN 10/535,232.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to the same or nearly the same composition comprising IgG Fc fragment. As such, the copending claims would anticipate or render obvious of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/

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Primary Examiner, Art Unit 1644

Chun Dahle, Ph.D. (formerly Chun Crowder)

Patent Examiner

June 5, 2008